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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,215	06/24/2003	Neema M. Kulkarni	PC 21501B	2258

28880 7590 06/21/2005

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EXAMINER	
COOK, REBECCA	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,215	KULKARNI ET AL.	
	Examiner	Art Unit	
	Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/30/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2005 has been entered.

Claim Rejections - 35 USC § 112

Claims 1-14 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the GABA analogs disclosed in the specification, does not reasonably provide enablement for any and all GABA analogs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404):

1) Nature of invention, 2) State of prior art, 3) Level of ordinary skill in the art, 4) Level of predictability in the art, 5) Amount of direction and guidance provided by the inventor, 6) Existence of working examples, 7) Breadth of claims, 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1) Nature of the invention.

The claims are drawn to compositions comprising GABA analogs, methods for preparing and using them.

2) State of the prior art.

Applicants disclose that the the lactams of GABA analogs gabapentin and pregabalin display toxicity. The specification discloses on pages 6-8 intended useful analogs of GABA. However, it is not clear if lactams of said analogs are intended to be included or excluded from the instant invention.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The number of analogs of GABA are innumberable.

4) Level of predictability in the art.

The art pertaining to which analogs of GABA would be active and yield the method of claim 16 is unpredictable.

5) Amount of direction and guidance provided by the inventor.

It is not clear if lactams of said analogs are intended to be included or excluded from the instant invention.

6) Existence of working examples.

The specification discloses pages 6-8 intended useful analogs of GABA. All of them are bicyclic aminomethyl acetic acid derivatives. It is not clear if compounds other than bicyclic aminomethyl acetic acid derivatives would yield the instant invention.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible GABA analogs.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could make the recited composition or perform the method of use without undue experimentation, see In re Armbruster 185 USPQ 152 CCPA 1975.

Claims 1-14 and 16 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising specific GABA analogs and a method for their use, does not reasonably provide enablement for said composition when it contains a polyhydric alcohol for the reason given in the Office Action of February 28, 2005. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants argue that that compositions containing xylitol, samples "e" and "f" in Table 4 of WO 99/59573 do not fall within claims 1-14 and 15, but do not explain why. This is not persuasive, since the amounts of gabapentin to polyhydric alcohols are within those of the claims.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear which disorders are intended to be included. Amending the conditions to recite a Markush group and using a semicolon to separate each kind of condition, will overcome this rejection, if this is the intent of the Applicants. For example, "A method of treating a subject suffering from a condition selected from the group consisting of a cerebral disease including...; [is the intent that cranial trauma depression, mania etc are cerebral diseases?]; inflammation; renal colic; insomnia; gastrointestinal damage; incontinence; [etc] and skeletal pain, the method..."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/59573 for the reasons given in the Office Actions of September 13, 2004 and February 28, 2005.

Applicants argue that WO 99/59573 does not suggest the limitations of polyhydric alcohol or pH in the composition or that said limitations would result in a stable liquid pharmaceutical composition and to support this had submitted a declaration under 37 CFR 1.132. The Declaration of May 27, 2005 by Dr. Mahjour has

been carefully considered, but is does not disclose the amounts of glycerol and xylitol in the composition or whether they are used alone or in combination and is persuasive only for when the initial pH is as shown in Table I. Furthermore, it only discloses results for when the GABA analog is gabapentin and the polyhydric alcohols are xylitol and glycerol.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook

Primary Examiner
Art Unit 1614

June 17, 2005